



PTO/SB/08B (07-06)
Approved for use through 09/30/2006. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
In accordance with the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
		Application Number	10/806,346		
		Filing Date	March 23, 2004		
		First Named Inventor	Jochen URTHALER		
		Art Unit	1636		
		Examiner Name	McGillen, Laura L.		
Sheet	1	of	3	Attorney Docket Number	0652.2620001/EKS/AES

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²	
/LLM/	NPL1	ASENJO, J.A., and ANDREWS, B.A., "Enzymatic Cell Lysis for Product Release," in <i>Separation Processes in Biotechnology</i> , Asenjo, J.A., ed., Marcel Dekker, Inc., New York, NY, pp. 143-175 (1990)		
/LLM/	NPL2	BIRNBOIM, H.C., and DOLY, J., "A rapid alkaline extraction procedure for screening recombinant plasmid DNA," <i>Nucleic Acids Res.</i> 7:1513-1523, Information Retrieval Limited (1979)		
/LLM/	NPL3	CARLSON, A., et al., "Mechanical Disruption of <i>Escherichia coli</i> for Plasmid Recovery," <i>Biotechnol. Bioeng.</i> 48:303-315, John Wiley & Sons, Inc. (1995)		
/LLM/	NPL4	CICCOLINI, L.A.S., et al., "Time Course of SDS-Alkaline Lysis of Recombinant Bacterial Cells for Plasmid Release," <i>Biotechnol. Bioeng.</i> 60:768-770, John Wiley & Sons, Inc. (1998)		
/LLM/	NPL5	CICCOLINI, L.A.S., et al., "A Mass Balance Study to Assess the Extent of Contaminant Removal Achieved in the Operations for the Primary Recovery of Plasmid DNA from <i>Escherichia coli</i> Cells," <i>Biotechnol. Bioeng.</i> 77:796-805, John Wiley Sons, Inc. (March 2002)		
/LLM/	NPL6	CHASE, H.A., "Purification of proteins by adsorption chromatography in expanded beds," <i>Trends Biotechnol.</i> 12:296-303, Elsevier Science Ltd. (1994)		
/LLM/	NPL7	DIOGO, M.M., et al., "Separation and Analysis of Plasmid Denatured Forms Using Hydrophobic Interaction Chromatography," <i>Anal. Biochem.</i> 275:122-124, Academic Press (1999)		
/LLM/	NPL8	FERREIRA, G.N.M., et al., "Development of Process Flow Sheets for the Purification of Supercoiled Plasmids for Gene Therapy Applications," <i>Biotechnol. Prog.</i> 15:725-731, American Chemical Society and American Institute of Chemical Engineers (1999)		
/LLM/	NPL9	FERREIRA, G.N.M., et al., "Anion exchange purification of plasmid DNA using expanded bed adsorption," <i>Bioseparation</i> 9:1-6, Kluwer Academic Publishers (2000)		
/LLM/	NPL10	FOSTER, D., "Cell Disruption: Breaking Up is Hard to Do," <i>Biotechnology</i> 10:1539-1541, Nature Publishing Co. (1992)		
Examiner Signature	/Laura McGillen/		Date Considered	06/20/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Application Number	10/806,346
		Filing Date	March 23, 2004
		First Named Inventor	Jochen URTHALER
		Art Unit	1636
		Examiner Name	McGille, Laura L.
Sheet	2	of	3
		Attorney Docket Number	0652.2620001/EKS/AES

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
/LLM/	NPL11	LEVY, M.S., <i>et al.</i> , "Effect of shear on plasmid DNA in solution," <i>Bioprocess Eng.</i> 20:7-13, Springer-Verlag (1999)	
/LLM/	NPL12	LEVY, M.S., <i>et al.</i> , "The effects of material properties and fluid flow intensity on plasmid DNA recovery during cell lysis," <i>Chem. Eng. Sci.</i> 54:3171-3178, Elsevier Science Ltd. (1999)	
/LLM/	NPL13	MARQUET, M., <i>et al.</i> , "Process Development for the Manufacture of Plasmid DNA Vectors for Use in Gene Therapy," <i>BioPharm.</i> 20:26-37, UCB-Bioproducts S.A. (1995)	
/LLM/	NPL14	PRAZERES, D.M.F., <i>et al.</i> , "Large-scale production of pharmaceutical-grade plasmid DNA for gene therapy: problems and bottlenecks," <i>Trends Biotechnol.</i> 17:169-174, Elsevier Science (1999)	
/LLM/	NPL15	RUSH, M.G., and WARNER, R.C., "Alkali Denaturation of Covalently Closed Circular Duplex Deoxyribonucleic Acid," <i>J. Biol. Chem.</i> 245:2704-2708, The American Society of Biological Chemists, Inc. (1970)	
/LLM/	NPL16	THEODOSSIOU, I., <i>et al.</i> , "The processing of a plasmid-based gene from <i>E. Coli</i> . Primary recovery by filtration," <i>Bioprocess Eng.</i> 16:175-183, Springer-Verlag (1997)	
/LLM/	NPL17	THEODOSSIOU, I., <i>et al.</i> , "Methods of enhancing the recovery of plasmid genes from neutralised cell lysate," <i>Bioprocess Eng.</i> 20:147-156, Springer-Verlag (1999)	
/LLM/	NPL18	VARLEY, D.L., <i>et al.</i> , "Production of plasmid DNA for human gene therapy using modified alkaline cell lysis and expanded bed anion exchange chromatography," <i>Bioseparation</i> 8:209-217, Kluwer Academic Publishers (1999)	
/LLM/	NPL19	Dialog File 351, Derwent World Patents Index, Accession No. 6383967, English language abstract for WO 93/11218 A1 and EP 0 875 271 A2 (Documents FP2 and FP12 on accompanying PTO/SB/08A)	
/LLM/	NPL20	Dialog File 351, Derwent World Patents Index, Accession No. 7564643, English language abstract for WO 96/08500 A1 (Document FP5 on accompanying PTO/SB/08A)	

Examiner Signature	/Laura McGille/	Date Considered	06/20/2007
--------------------	-----------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449B/P'TO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/806,346
Filing Date	March 23, 2004
First Named Inventor	Jochen URTHALER
Art Unit	1636
Examiner Name	McGille, Laura L.
Attorney Docket Number	0652.2620001/EKS/AES

Sheet	3	of	3
-------	---	----	---

NON PATENT LITERATURE DOCUMENTS

[illegible]

604041_1

604041_1		Date Considered	06/20/2007
Examiner Signature	/Laura McGillem/	<input type="checkbox"/> If this citation is in conformance with MPEP 609. Draw line through citation if not in conformance and	

Examiner's Signature	/Laura McGillem/	Confidentiality
----------------------	------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

37 CFR 1.98 (1-800-786-9199) and select option 2.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



(Use as many sheets as necessary)

Sheet	1	of	3
-------	---	----	---

Equivalent of Form PTO/SB/08A (07-06)
Approved for use through 09/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
This collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known

Application Number	10/806,346
Filing Date	March 23, 2004
First Named Inventor	Jochen URTHALER
Art Unit	1636
Examiner Name	McGillem, Laura L.
Attorney Docket Number	0652.2620001/EKS/AES

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ² Number ³ Kind Code ⁴ (if known)				
/LLM/	FP1	EP 0 376 080 A1	07/04/1990	Talent SRL		
/LLM/		WO 93/11218 A1	06/10/1993	Diagen Institut Für Molekularbiologische Diagnostik GmbH		Abs
	FP2					
/LLM/	FP3	WO 95/21250 A2	08/10/1995	Vical Incorporated		
/LLM/	FP4	WO 96/02658 A1	02/01/1996	Merck & Co., Inc.		
/LLM/	FP5	WO 96/08500 A1	03/21/1996	Qiagen GmbH		Abs
/LLM/	FP6	WO 96/21729 A1	07/18/1996	Vical Incorporated		
/LLM/	FP7	WO 96/36706 A1	11/21/1996	Merck & Co., Inc.		
/LLM/	FP8	WO 97/23601 A1	07/03/1997	Genzyme Corporation		
/LLM/	FP9	WO 97/29190 A1	08/14/1997	Therexsys Limited		

Examiner Signature	/Laura McGillem/	Date Considered	06/20/2007
--------------------	------------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *Applicant's unique citation designation number (optional). * See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. * Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). * For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. * Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. * Applicant is to place a check mark here if English language Translation is attached.

document by the appropriate agency, and the information is not required to be submitted to the USPTO. If you are submitting information to the USPTO, English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you are completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.18 if possible. ⁵ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449A/PTO

(Use as many sheets as necessary)

Sheet	3	of	3
-------	---	----	---

Application Number	10/806,346
Filing Date	March 23, 2004
First Named Inventor	Jochen URTHALER
Art Unit	1636
Examiner Name	McGille, Laura L.
Attorney Docket Number	0652.2620001/EKS/AES

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ² Number ³ Kind Code ³ (if known)				
/LLM/	FP18	WO 01/07599 A1	02/01/2001	Genentech, Inc.		
/LLM/	FP19	WO 02/04027 A1	01/17/2002	Instituto Superior Tecnico		
/LLM/	FP20	WO 02/057446 A2	07/25/2002	Drm, Dr. Müller AG		Abs
/LLM/	FP21	WO 02/26966 A2	04/04/2002	Ecole Polytechnique Federale de Lausanne		

603980_1

Examiner
Signature

/Laura McGillem/

Date
Considered

06/20/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *Applicant's unique citation designation number (optional). * See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. * Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). * For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. * Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. * Applicant is to place a check mark here if English language Translation is attached.

document by the appropriate symbols as indicated on the document under "W" or "C".
English language Translation is attached.
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.